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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; SALIX PHARMACEUTICALS, INC.; PROGENICS PHARMACEUTICALS, INC.; and WYETH LLC, formerly known as WYETH, Plaintiffs, v. ACTAVIS LABORATORIES FL, INC.; ACTAVIS LLC; TEVA PHARMACEUTICALS USA, INC.; and TEVA PHARMACEUTICALS INDUSTRIES LTD., Defendants.	Civil Action No. 17-12857 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals International, Inc. ("Valeant"), Salix Pharmaceuticals, Inc. ("Salix"), Progenics Pharmaceuticals, Inc. ("Progenics"), and Wyeth LLC (collectively "Plaintiffs") by way of Complaint against Defendants Actavis Laboratories FL, Inc. ("Actavis FL"), Actavis LLC, Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceuticals Industries Ltd. ("Teva Ltd.") (collectively "Actavis" or "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Valeant is a corporation organized and existing under the laws of Canada. Its United States headquarters are located at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

2. Plaintiff Salix is a corporation organized and existing under the laws of California, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, NC 27615. Salix is the registered holder of approved New Drug Application No. 208271, which covers Relistor® tablets.

3. Plaintiff Progenics is a corporation organized and existing under the laws of Delaware, having its principal place of business at One World Trade Center, 47th Floor, New York, NY 10007.

4. Plaintiff Wyeth LLC, formerly Wyeth, is a Delaware LLC, having places of business at 235 East 42nd Street, New York, NY 10017, and One Giralda Farms, Madison, NJ 07940.

5. Upon information and belief, Defendant Actavis FL is a corporation organized and existing under the laws of Florida, having its a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

6. Upon information and belief, Defendant Actavis LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

7. Upon information and belief, Defendant Teva USA is a corporation organized and existing under the laws of Delaware, having a place of business at 1090 Horsham Road, North Wales, PA 19454.

8. Upon information and belief, Defendant Teva Ltd., is a publicly-traded company organized and existing under the laws of Israel, having a place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva 4951033, Israel.

9. Upon information and belief, Actavis FL and Actavis LLC are wholly-owned subsidiaries of Teva USA, which is a wholly-owned subsidiary of Teva Ltd.

NATURE OF THE ACTION

10. This is an action for infringement of United States Patent Nos. 9,724,343 ("the '343 patent") and 9,492,445 ("the '445 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Actavis's filing of an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic methylnaltrexone bromide tablets, 150 mg ("Actavis's generic methylnaltrexone bromide tablets").

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

12. Upon information and belief, this Court has jurisdiction over Actavis FL. Upon information and belief, Actavis FL is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis FL directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic methylnaltrexone bromide tablets. Upon information and

belief, Actavis FL has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Upon information and belief, Actavis FL has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

13. Upon information and belief, this Court has jurisdiction over Actavis LLC. Upon information and belief, Actavis LLC is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis LLC directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic methylnaltrexone bromide tablets. Upon information and belief, Actavis LLC's principal place of business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Upon information and belief, Actavis LLC is registered in the State of New Jersey as a "wholesale[r]" of drugs, with Registration No. 5003899. Upon information and belief, Actavis LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. Upon information and belief, this Court has jurisdiction over Teva USA. Upon information and belief, Teva USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva USA directly, or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district, and this judicial district is the likely destination for Actavis's generic methylnaltrexone bromide tablets. Upon information and belief, Teva USA operates and maintains branches in Fairfield, New Jersey; Woodcliff Lake,

New Jersey; and Parsippany, New Jersey. Upon information and belief, Teva USA is registered in the State of New Jersey as a "wholesale[r]" and "manufacturer and wholesale[r]" of drugs, with Registration Nos. 5003436 and 5000583. Upon information and belief Teva USA is registered to do business in New Jersey under New Jersey Entity ID No. 0100250184 and purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Teva USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing actions in this jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction.

15. Upon information and belief, this Court has jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Ltd. intentionally markets and provides its generic pharmaceutical products to residents of this State, enjoys substantial income from this State, and maintains a physical presence within this State at least through its wholly-owned subsidiary Teva USA. Upon information and belief, Teva Ltd. has further previously availed itself of this Court by filing actions in this jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction.

16. Upon information and belief, Defendants have a regular and established place of business in this judicial district because, for example, Actavis FL and Actavis LLC maintain places of business in this judicial district.

17. Upon information and belief, Actavis FL, Actavis LLC, Teva USA and Teva Ltd. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and

distributing generic products in the United States. Upon information and belief, Actavis FL, Actavis LLC, Teva USA and Teva Ltd. operate as a single integrated business.

18. Actavis's ANDA No. 209615 is the subject of an on-going infringement litigation in the District of New Jersey: *Valeant Pharmaceuticals et al. v. Actavis Laboratories FL., Inc.*, Civil Action No. 2:16-cv-09038.

19. Teva USA and Teva Ltd. availed themselves of the rights, benefits, and privileges of this Court by filing complaints in the District of New Jersey in at least the following actions: *Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civil Action No. 3:17-cv-00517 (Teva USA and Teva Ltd.); *Teva Pharmaceuticals USA, Inc. et al. v. Sandoz, Inc. et al.*, Civil Action No. 3:17-cv-00275 (Teva USA and Teva Ltd.); and *Teva Pharmaceutical USA, Inc. et al. v. Synthon Pharmaceuticals, Inc. et al.*, Civil Action No. 2:15-cv-00472 (Teva USA and Teva Ltd.).

20. Actavis FL, Actavis LLC, Teva USA, and/or Teva Ltd. consented to or did not contest the jurisdiction of this Court, for example, in at least the following District of New Jersey actions: *Valeant Pharmaceuticals Int'l, Inc. v. Actavis LLC*, Civil Action Nos. 2:16-cv-00889-SRCCLW, 2:15-cv-08353-SRC-CLW (Actavis LLC); *Rhodes Pharmaceuticals L.P. v. Actavis, Inc. et al.*, Civil Action No. 2:16-cv-02667 (WHW-CLW) (Actavis LLC); *Abraxis Bioscience, LLC et al. v. Actavis LLC*, Civil Action No. 2:16-cv-01925 (JMV) (MF) (Actavis LLC); *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, Civil Action No. 3:15-cv-03107-MAS-LHG (Actavis LLC); *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:15-cv-06401 (SRC)(CLW) (Teva USA); *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 3:14-cv-07811 (MLC)(TJB) (Teva USA and Teva Ltd.); *Novo Nordisk Inc. et al. v. Teva*

Pharmaceuticals USA, Inc., Civil Action No. 3:14-cv-04248 (MAS)(DEA) (Teva USA); *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 1:14-cv-06398 (JBS)(KMW) (Teva USA); *United Therapeutics et al. v. Actavis Laboratories FL, Inc.*, Civil Action No. 3:16-cv-01816-PGS-LHG (Actavis FL); *Sebela International Ltd. et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:17-cv-04789-CCC-MF (Actavis FL, Teva USA and Teva Ltd.); *Valeant Pharmaceuticals International, Inc. et al. v. Actavis Laboratories FL, Inc.*, Civil Action No. 2:16-cv-09038-SRC-CLW (Actavis FL); and *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, Civil Action No. 2:15-cv-06934 (SRC/CLW) (Actavis FL).

21. Actavis FL, Actavis LLC, Teva USA, and/or Teva Ltd. availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims, for example, in at least the following prior District of New Jersey actions: *Rhodes Pharmaceuticals L.P. v. Actavis, Inc. et al.*, Civil Action No. 2:16-cv-02667 (WHW-CLW) (Actavis LLC); *Abraxis Bioscience, LLC et al. v. Actavis LLC*, Civil Action No. 16-cv-01925 (JMV) (MF) (Actavis LLC); *Valeant Pharmaceuticals Int'l, Inc. v. Actavis LLC*, Civil Action Nos. 2:16-cv-00889-SRC-CLW, 2:15-cv-08353-SRC-CLW (Actavis LLC); *Novo Nordisk Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 3:14-cv-04248 (MAS)(DEA) (Teva USA); *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 1:14-cv-06398 (JBS)(KMW) (Teva USA); *AstraZeneca Pharmaceuticals LP et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 3:07-cv-03001 (Teva USA and Teva Ltd.); *United Therapeutics et al. v. Actavis Laboratories FL, Inc.*, Civil Action No. 3:16-cv-01816-PGS-LHG (Actavis FL); *Sebela International Ltd. et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:17-cv-04789-CCC-MF (Actavis FL); *Valeant Pharmaceuticals International, Inc. et al. v. Actavis Laboratories FL,*

Inc., Civil Action No. 2:16-cv-09038-SRC-CLW (Actavis FL); and *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, Civil Action No. 2:15-cv-06934 (SRC/CLW) (Actavis FL).

22. Upon information and belief, venue is proper in this judicial district under 28 U.S.C.§§ 1391(c) and (d), and § 1400(b).

23. Actavis FL, Actavis LLC, Teva USA, and/or Teva Ltd. did not contest venue in this judicial district in at least the following actions: *Valeant Pharmaceuticals Int'l, Inc. v. Actavis LLC*, Civil Action Nos. 2:16-cv-00889-SRC-CLW, 2:15-cv-08353-SRC-CLW (Actavis LLC); *Rhodes Pharmaceuticals L.P. v. Actavis, Inc. et al.*, Civil Action No. 2:16-cv-02667 (WHW-CLW) (Actavis LLC); *Abraxis Bioscience, LLC et al. v. Actavis LLC*, Civil Action No. 16-cv-01925 (JMV) (MF) (Actavis LLC); *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, Civil Action No. 3:15-cv-03107-MAS-LHG (Actavis LLC); *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:15-cv-06401 (SRC)(CLW) (Teva USA); *Novo Nordisk Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 3:14-cv-04248 (MAS)(DEA) (Teva USA); and *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 3:14-cv-07811 (MLC)(TJB) (Teva USA and Teva Ltd.); *United Therapeutics et al. v. Actavis Laboratories FL, Inc.*, Civil Action No. 3:16-cv-01816-PGS-LHG (Actavis FL); *Sebela International Ltd. et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:17-cv-04789-CCC-MF (Actavis FL, Teva USA and Teva Ltd.); *Valeant Pharmaceuticals International, Inc. et al. v. Actavis Laboratories FL, Inc.*, Civil Action No. 2:16-cv-09038-SRC-CLW (Actavis FL); and *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, Civil Action No. 2:15-cv-06934 (SRC/CLW) (Actavis FL).

THE PATENT IN SUIT

24. The U.S. Patent and Trademark Office ("PTO") issued the '445 patent on November 15, 2016. The '445 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '445 patent and have the right to sue for infringement thereof. A copy of the '445 patent is attached hereto as Exhibit A.

25. The PTO issued the '343 patent on August 8, 2017. The '343 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '343 patent and have the right to sue for infringement thereof. A copy of the '343 patent is attached hereto as Exhibit B.

26. Salix is the holder of New Drug Application ("NDA") No. 208271 for Relistor® tablets. In conjunction with NDA No. 208271, the '445 and '343 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), together with U.S. Patent Nos. 8,420,663, 8,524,276, 8,956,651, 9,180,125, and 9,314,461, which are the subject of an on-going infringement litigation in the District of New Jersey: *Valeant Pharmaceuticals et al. v. Actavis Laboratories FL., Inc.*, Civil Action No. 2:16-cv-09038.

27. Methylnaltrexone bromide tablets, 150 mg, are sold in the United States under the trademark Relistor®.

ACTAVIS'S INFRINGING ANDA SUBMISSION

28. Upon information and belief, Actavis filed or caused to be filed with the FDA ANDA No. 209615, under section 505(j) of the Act and 21 U.S.C. § 355(j).

29. Upon information and belief, Actavis's ANDA No. 209615 seeks FDA approval to sell in the United States Actavis's generic methylnaltrexone bromide tablets, intended to be a generic version of Relistor®.

30. Valeant, Salix, Progenics, and Wyeth LLC received a letter from Actavis FL dated October 24, 2017, purporting to be a Notice of Certification for ANDA No. 209615 ("Actavis's notice letter) under Section 505(j)(2)(B)(iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(iv)(I), and 21 C.F.R. § 314.95(c). Actavis's notice letter was addressed to Valeant Pharmaceuticals North America LLC at Bridgewater NJ and Salix Pharmaceuticals, Inc. at Bridgewater, NJ.

31. Actavis's notice letter states that "Actavis Laboratories FL, Inc. [is] an indirect wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc."

32. Actavis's notice letter alleges that Actavis has submitted to the FDA ANDA No. 209615 seeking FDA approval to sell Actavis's generic methylnaltrexone bromide tablets, intended to be a generic version of Relistor®.

33. Actavis's notice letter states that Actavis's ANDA No. 209615 "contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver" for Actavis's generic methylnaltrexone bromide tablets.

34. Actavis's notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defense, provides no explanation of any non-infringement defense related to claims 1-9, 12-18, and 20 of the '343 patent.

35. The '445 and '343 patents are listed in the Orange Book in conjunction with NDA. No. 208271 for oral Relistor®.

36. Upon information and belief, ANDA No. 209615 seeks approval of Actavis's generic methylnaltrexone bromide tablets that are the same, or substantially the same, as Relistor® 150 mg tablets.

37. Upon information and belief, Actavis FL's actions related to ANDA No. 209615 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Actavis LLC, Teva USA, and Teva Ltd.

COUNT I AGAINST ACTAVIS

Infringement of the '445 Patent Under § 271(e)(2)

38. Paragraphs 1-37 are incorporated herein as set forth above.

39. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '445 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209615 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '445 patent.

40. Upon information and belief, Actavis's generic methylnaltrexone bromide tablets will, if approved and marketed, infringe at least one claim of the '445 patent.

41. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

COUNT II AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '445 Patent

42. Paragraphs 1-41 are incorporated herein as set forth above.

43. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

44. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

45. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '445 patent, including Actavis's filing of ANDA No. 209615.

46. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

47. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will constitute infringement of at least one claim of the '445 patent.

COUNT III AGAINST ACTAVIS

Infringement of the '343 Patent Under § 271(e)(2)

48. Paragraphs 1-47 are incorporated herein as set forth above.

49. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '343 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209615 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '343 patent.

50. Upon information and belief, Actavis's generic methylnaltrexone bromide tablets will, if approved and marketed, infringe at least one claim of the '343 patent.

51. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '343 patent.

COUNT IV AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '343 Patent

52. Paragraphs 1-51 are incorporated herein as set forth above.

53. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

54. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

55. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '343 patent, including Actavis's filing of ANDA No. 209615.

56. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '343 patent.

57. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will constitute infringement of at least one claim of the '343 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Actavis on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '445 patent by submitting or causing to be submitted ANDA No. 209615 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '445 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '343 patent by submitting or causing to be submitted ANDA No. 209615 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '343 patent;

3. Order that the effective date of any approval by the FDA of Actavis's generic methylnaltrexone bromide tablets be a date that is not earlier than the expiration of the '445 and '343 patents or such later date as the Court may determine;

4. Enjoin Actavis from the commercial manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide tablets until expiration of the '445 and '343 patents or such later date as the Court may determine;

5. Enjoin Actavis and all persons acting in concert with Actavis from seeking, obtaining, or maintaining approval of Actavis's ANDA No. 209615 until expiration of the '445 and '343 patents;

6. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

7. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: December 8, 2017
Newark, New Jersey

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